

K984348

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JAN 20 1999

ISOLA SPINAL SYSTEM

Pedicle Screw Indications

510(k) SUMMARY

COMPANY: DePuy AcroMed, Inc.
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME: TiMX Low Back System

CLASSIFICATION: Labeled for pedicle screw use: Class II

DESCRIPTION: The primary purpose of this premarket notification is to add indications to the marketing clearance for the pedicle screws which may be used as a spinal anchor in the TiMX Low Back System.

MATERIAL: All implant components are manufactured of ASTM F-136 titanium alloy.

INDICATIONS: The TiMX Low Back System when used with pedicle screws, in skeletally mature patients, is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The TiMX Low Back System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

The TiMX Low Back System when not used with pedicle screws, is intended for posterior hook, wire, and/or sacral/iliac screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed fusion surgery.

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**SUBSTANTIAL
EQUIVALENCE:**

The TiMX Low Back System manufactured from titanium alloy is substantially equivalent, for purposes of this 510(k) adding indications, to itself. This 510(k) seeks to add labeled indications pursuant to a reclassification order. The device design remains the same.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 20 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Pam Corsillo
Regulatory Submissions Associate
DePuy AcroMed, Inc.
3303 Carnegie Avenue
Cleveland, Ohio 44115

Re: K984348
Trade Name: TiMX Low Back System
K984350
Trade Name: VSP System
Regulatory Class: II
Product Codes: MNI, MNH, and KWP
Dated: December 3, 1998
Received: December 4, 1998

Dear Ms. Corsillo:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

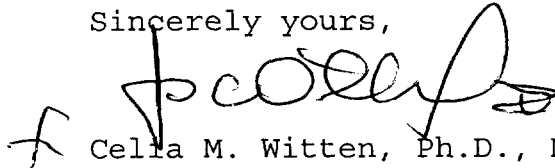
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K984348

Device Name: TiMX Low Back System (Titanium)

Indications for Use:

The TiMX Low Back System when used with pedicle screws, in skeletally mature patients, is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The TiMX Low Back System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRI, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General Restorative Devices
510(k) Number

K984348

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)